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PREPARATIONS FOR THE UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT ON THE BASIS OF GENERAL ASSEMBLY RESOLUTION 44/228 AND TAKING INTO ACCOUNT OTHER RELEVANT GENERAL ASSEMBLY RESOLUTIONS: CROSS-SECTORAL ISSUES

Environmentally sound management of biotechnology

(Section II, Chapter 8 of Agenda 21)

Report of the Secretary-General of the Conference

I. INTRODUCTION

1. The present document has been prepared in response to Preparatory Committee decision 3/19. It takes into account the proposals submitted by Governments in the light of that decision including the proposal contained in document A/CONF.151/PC/WG.I/L.26. The proposals are reproduced in full in document A/CONF.151/PC/109, which is before the Preparatory Committee at its present session. The present document draws upon advice provided by the ad hoc Workshop of Senior Experts on International Cooperation on the Environmentally Sound Application of Biotechnology, held at New Delhi from 23 to 25 October 1991, as well as upon advice and assistance received from

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* See A/CONF.151/PC/96.

many other expert organizations and individuals. It is based on the guidance provided by the Preparatory Committee on the structure of Agenda 21, as contained in its decision 3/2. Text that has been derived from part II of document A/CONF.151/WG.I/L.30/Rev.1 is contained within the symbols ‹ › and referenced.

2. ‹(Para. 2) Biotechnology is a set of enabling techniques to produce certain products. It is the integration of the new techniques emerging from modern biotechnology with the well-established approaches of traditional biotechnology. These will be required for the continued successful application of biotechnology in areas such as improving human health, increasing agricultural productivity and tackling environmental problems. 1/ By itself biotechnology cannot resolve all the fundamental problems of environment and development. Nevertheless, it has a significant contribution to make in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and the detoxification of hazardous wastes. Biotechnology also offers new opportunities for global partnerships, especially between the countries rich in biological resources (which include genetic resources) but lacking the expertise and investments needed to apply these through biotechnology and those which have developed the technological expertise to transform biological resources to serve the needs of sustainable development.› ‹(Para. 4) Biotechnology can assist in the conservation of those resources through, for example, ex situ techniques. The programme areas in this paper need to take continuing account not only of the development of section II, chapter 7 of Agenda 21 entitled "Conservation of biological diversity, but also of the progress made by the Intergovernmental Negotiating Committee for a Convention on Biological Diversity. The potential of biotechnology brings it into a close relationship with a wide spectrum of sectoral and cross-sectoral activities.› 2/ ‹(Para. 3) The programme areas set out below seek to foster an internationally agreed framework of safety to ensure the environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms, especially within developing countries, as follows:›

(a) Increasing productivity for food, feed and renewable raw materials;

(b) Improving human health;

(c) Enhancing protection of the environment;

(d) Enhancing safety and developing international mechanisms for cooperation;

(e) Establishing enabling mechanisms for the environmentally sound application of biotechnology.

II. PROGRAMME AREAS

A. Increasing productivity for food, feed and renewable raw materials

1. Basis for action

3. ‹(Para. 8) The global population is expected to double to about 10 billion by the middle of the next century, with 9 out of 10 people living in developing countries. 3/ The challenge is to double food production in the next 50 years, while simultaneously developing more sustainable agricultural systems. Much of this increased productivity will need to take place in developing countries. It will require the successful and environmentally safe applications of biotechnology in agriculture, in the environment and in human health care. Most of the investment in modern biotechnology has been in the industrialized world. Significant new investments and human resource development will be required in biotechnology, especially in the developing world.›

2. Objectives

4. The objectives are as follows:

(a) ‹(Para. 9 (a)) By the year [2000], using the combined resources of modern biotechnology and conventional plant/animal/microorganism improvement, increase the yield potential of major crops, livestock and aquaculture species and forest products by [15-20 per cent];›

(b) Reduce the need for volume increases of food, feed and raw materials by improving the nutritional value (composition) of the source crops, animals and microorganisms, and reduce post-harvest losses of plant and animal products;

(c) ‹(Para. 9 (b)) Increase the use of integrated pest management techniques to reduce the use of chemical pesticides and fertilizers;›

(d) ‹(Para. 9 (c)) Evaluate the agricultural potential of marginal lands in comparison with other potential uses (e.g., forestry, conservation). In those areas where agricultural use is desirable, develop systems allowing for substantial and sustainable productivity increases;›

(e) ‹(Para. 9 (d)) Promote the use of appropriate safety procedures based on programme area D;›

(f) Expand the applications of biotechnology in forestry, both for increasing yields of forest products and for improving afforestation and reforestation techniques.

3. Activities

(a) Management-related activities

5. ‹(Consolidation of paras. 10 (a), (b) and (c)) The main activity is to accelerate plant and animal breeding and microorganism improvement by the use of traditional and modern biotechnologies, to ensure sustainable agricultural output. 4/ More specifically, the following activities should be undertaken:

(a) Improve productivity, nutritional quality shelf-life of food, and animal feed products, including work on post-harvest physiology;

(b) Further develop resistance to diseases and pests;

(c) Develop plant varieties tolerant to abiotic stress, such as mineral toxicity (aluminium and salts), drought and other environmental stress;

(d) Increase the efficiency of symbiotic nitrogen fixation;

(e) Facilitate the safe exchange of plant, animal and microbial germ plasm by the development of improved diagnostic techniques and better methods for their rapid propagation;

(f) Develop improved diagnostic agents and vaccines for the prevention and spread of diseases and for rapid assessment of toxins or infectious organisms in products for human use or livestock feed;

(g) Identify more productive strains of fast-growing trees for fuelwood and develop rapid propagation methods to aid their wider dissemination and use;› 4/

(h) Evaluate the use of various biotechnology techniques to improve the yields of fish, algal and other aquatic species. Particular attention should be paid to how the use of biotechnology would impact on the maintenance of the aquatic environment's integrity;› 5/

(i) Provide additional support for germ plasm conservation and exchange activities as appropriate;

(j) Promote sustainable agricultural output by strengthening and broadening the scope of existing research centres to achieve the necessary critical mass by encouraging and monitoring research into the development of biological products and processes of productive and environmental value.

(b) Information and data

6. The following activities should be undertaken:

(a) ‹(Para. 10 (d)) Undertake comparative assessments of different technologies for food production, together with a system for assessing the

possible effects of biotechnologies on international trade in agricultural products;›

(b) ‹(Para. 10 (i)) Examine the implications of the withdrawal of subsidies and the possible use of other economic instruments to reflect the environmental costs associated with the unsustainable use of pesticides.›

(c) International and regional cooperation and coordination

7. The following activities should be undertaken:

(a) ‹(Para. 10 (f)) Examine the policy implications for international cooperation on issues related to the conservation and exchange of germ plasm, intellectual property rights, access to the benefits of biotechnology and the international harmonization of bio-safety procedures;› 6/

(b) ‹(Para. 10 (g)) Promote international, including regional, collaborative research programmes, especially in developing countries, to support activities outlined in this programme area, with particular reference to assistance for local and indigenous communities in the conservation and sustainable use of biological resources;›

(c) ‹(Para. 10 (e)) Accelerate technology acquisition, transfer and adaptation through international cooperation to support the activities in this programme area.›

4. Means of implementation

(a) Financing and cost evaluation

8. The estimated average annual cost of this programme area for the period 1993-2000 could be upwards of US$ 5 billion, of which it is estimated that about US$ 50 million would come from international financing sources. Most of the amount for this programme area is included in the cost evaluation of other chapters. 7/ Both the total amount and the proportion of global investments currently made by developing countries in biotechnology research and development need to be increased significantly over the period 1993-2000 and beyond to enable them to take advantage of the increasing opportunities that biotechnology has to offer for accelerated development.

(b) Scientific and technological means

9. See paragraphs 6 and 7 above.

(c) Human resource development

10. Training of competent professionals at all levels (including scientific personnel, technical staff and extension workers) is one of the most essential components of any programme of this kind. Continuing programmes of formal

training for scientists should include managerial training, given the importance of good management of research resources for the successful completion of large multidisciplinary projects. Training programmes should also be developed, within the context of specific projects, to meet regional or national needs for comprehensively trained personnel capable of using advanced technology to reduce the "brain drain" from developing to developed countries. Emphasis should be given to encouraging collaboration between scientists, extension workers and users to produce integrated systems. Additionally, special consideration should be given to the execution of programmes for training and exchange of knowledge on traditional biotechnologies.

(d) Capacity-building

11. Institutional upgrading or other appropriate measures will be needed to build up technical, managerial, planning and administrative capacities at the national level to support the activities in this programme area. This should be backed up by adequate international, scientific, technical and financial assistance to facilitate technical cooperation and raise the capacities of the developing countries. Programme area E contains further details.

B. Improving human health

1. Basis for action

12. ‹(Para. 11) The improvement of human health is one of the most important objectives of development. The deterioration of environmental quality, notably air, water and soil pollution due to toxic chemicals, hazardous wastes, radiation and other sources, is a matter of growing concern. This degradation of the environment resulting from inadequate or inappropriate development has a direct negative effect on human health. Malnutrition, demographic pressures which include poor human settlements, lack of good quality potable water and inadequate sanitation facilities add to the problems of communicable and non-communicable diseases. Experimentation with unsafe fertility-regulating drugs on women in some developing countries is a particularly acute problem. As a consequence, the health and well-being of people are exposed to increasing pressures.› In certain essential areas, R&D in modern biotechnology has moved from the public to the private domain and has become increasingly expensive. This has further widened the health gap between the rich and poor communities. ‹(Para. 12) There is a need to accelerate effectively the appropriate applications of development to which biotechnology can contribute.›

2. Objectives

13. ‹(Para. 13) The main objective of this programme area is to achieve good health for all by the end of the century and, more specifically:

(a) To promote good general health among people of all ages;

(b) To strengthen or inaugurate programmes as a matter of urgency to protect the world population against major communicable diseases by the year [2000];

(c) To develop programmes for specific treatment and protection from major non-communicable diseases;

(d) To adopt appropriate safety procedures based on programme area D.›

3. Activities

(a) Management-related activities

14. National Governments with the active involvement of the appropriate United Nations organizations, other intergovernmental and non-governmental organizations, academic and scientific institutions, as well as the pharmaceutical industry, should undertake the following activities:

(a) Develop national and international programmes for identifying and targeting those populations of the world most in need of improvement in general health and protection from diseases;

(b) Develop criteria for monitoring and evaluating the effectiveness and safety of the proposed activities;

(c) ‹(Para. 14 (g)) Develop new fertility-regulating mechanisms and agents which are safe and reversible and which are long-lasting, particularly for men. Whenever feasible, facilitate local production of these agents;›

(d) Establish and enforce procedures to screen, monitor and bar unsafe drugs and medical technologies used on women in developing countries for purposes of experimentation in reproductive processes;

(e) Improve and monitor drinking water quality by introducing appropriate specific measures, including diagnostics based on immunological assays and DNA probes for detection of viral, parasitic and bacterial pathogens and their products;

(f) ‹(Para. 14 (a)) Develop new and improved vaccines against major communicable diseases which are efficient, safe and offer protection with a minimum number of doses;› 8/

(g) Develop biodegradable delivery systems for vaccines that eliminate the need for present multiple-dose schedules, facilitate better coverage of the population and reduce the costs of immunization;

(h) Intensify efforts to develop a multi-component vaccine conferring protection against common diseases of children;

(i) ‹(Para. 14 (b)) Develop effective biological control agents against disease-transmitting vectors, such as mosquitoes and resistant variants, taking account of environmental protection considerations;›

(j) ‹(Para. 14 (c)) Develop new diagnostics based on, for example, monoclonal antibodies and DNA probes to enable early detection of communicable, non-communicable and genetic disorders;›

(k) ‹(Paras. 14 (e), (f)) Develop and facilitate the use of recombinant hormones;› 9/

(l) ‹(Para. 14 (h)) Develop new drugs for resistant organisms and for metabolic disorders;› 10/

(m) ‹(Para. 14 (i)) Develop improved delivery systems for the administration of therapeutics and prophylactics;› 11/

(n) ‹(Para. 14 (j)) Develop safe and effective methods for the treatment of genetic disorders;›

(o) Develop more effective utilization of medicinal plants.

(b) Data and information

15. The following activities should be undertaken:

(a) ‹(Para. 14 (k)) Undertake research to assess the comparative social and financial advantages of different technologies for basic and reproductive health care within a framework of universal safety and ethical standards;›

(b) Develop public education programmes to encourage awareness and understanding of modern biotechnology.

(c) International and regional cooperation and coordination

16. The following activity should be undertaken:

‹(Para. 14 (n)) Develop international harmonized safety procedures based on programme area D.›

4. Means of implementation

17. To achieve the above goals, the activities need to be implemented with urgency if major communicable diseases are to be controlled by the beginning of the next century. The spread of some diseases to all regions of the world calls for global measures. For more localized diseases, regional or national policies will be more appropriate. This calls for:

(a) Continuous political commitment;

(b) National priorities with a defined time-frame;

(c) Scientific and financial inputs at global and national levels.

(a) Financing and cost evaluation

18. The estimated average annual cost of this programme area could be upwards of US$ 14 billion, of which it is estimated that about US$ 130 million would come from international financing sources.

(b) Scientific and technological means

19. Well-coordinated multidisciplinary efforts will be required. At the global level, this may mean collaboration between research institutions and industry in different countries, with funding at the intergovernmental level, possibly supported by similar collaboration at the national level. Alternatively, task forces could be charged with the development of a biotechnological product from the laboratory through to its application in the field within a set time-frame. R&D support will also need to be strengthened, together with the mechanisms for providing the transfer of relevant technology. Product development should receive priority for new diagnostics, biological therapeutics and second generation vaccines for diseases of local importance. Industrial collaboration could be brought in at any stage of development. The establishment of biotechnology groups or consortia, involving cooperation between scientists, financial institutions and industries, should be considered to facilitate the development of cheaper, new, affordable techniques.

(c) Human resource development

20. ‹(Para. 14 (d)) Training and technology transfer is needed at the global level, with access to, and exchange of, information and expertise between regions and countries, particularly of indigenous or traditional knowledge. The training of personnel could be undertaken at three levels:

(a) Scientists required for basic and product-orientated research;

(b) Health personnel in the use of new products;

(c) Tertiary level technical workers for delivery in the field.›

(d) Capacity-building

21. See programme area E.

C. Enhancing protection of the environment

1. Basis for action

22. ‹(Consolidation of paras. 15 and 16) Environmental protection is an integral component of sustainable development. The environment is threatened in all its biotic and abiotic components: animals, plants, microbes and ecosystems comprising biological diversity; water, oil and air, which form the physical components of habitats and ecosystems; and all the interactions between the components of biodiversity and their sustaining habitats and ecosystems. With the continued increase in the use of chemicals, energy and renewable and other non-renewable resources by an expanding global population, associated environmental problems will also increase. Despite increasing efforts to prevent waste accumulation and to promote recycling, the amount of environmental damage caused by over-consumption, the quantities of waste generated and the degree of unsustainable land use appear likely to continue growing.›

23. ‹(Para. 17) The need for a diverse genetic pool of plant, animal and microbial germ plasm for sustainable development is well established. Biotechnology is one of many tools that can play an important role in supporting the rehabilitation of degraded ecosystems and landscapes. This may be done through the development of new techniques for reforestation, germ plasm conservation, and new plant varieties suitable for fragile environments. Biotechnology can also contribute to the study of the effects that organisms introduced into degraded ecosystems have on the remaining organisms and on other organisms.›

2. Objectives

24. ‹(Para. 18) The aim of this programme is to prevent, halt and reverse environmental degradation through the use of biotechnology and other technologies, while supporting safety procedures as an integral component of the programme.› Specific objectives include the inauguration of specific programmes with incremental targets by or before the year [1995] to:

(a) Adopt production processes making optimal use of natural resources, by recycling biomass, recovering energy and minimizing waste generation;

(b) Promote remedial measures, with priority in the areas of bio-remediation of land and water, waste treatment, soil conservation, reforestation, afforestation and land rehabilitation;

(c) Apply biotechnology to conserve environmental integrity with a view to long-term ecological security and with the conservation of biological diversity as a priority.

25. The activities set out below should commence or be reinforced immediately and should include the development of appropriate performance criteria to allow environmentally sound applications to be identified.

3. Activities

(a) Management-related activities

26. National Governments should act with appropriate United Nations organizations, other governmental and non-governmental organizations, private sector, academic and scientific institutions, bilateral and multilateral development agencies, and relevant environmental agencies, to develop biotechnologies in support of other technologies to develope and improve detection and monitoring techniques which provide essential knowledge on the state of the environment. Activities should include:

(a) ‹(Consolidation of paras. 19 (h) and (h) bis) Develop environmentally sound alternatives and improvements for environmentally damaging production processes;› 12/

(b) ‹(Consolidation of paras. 19 (c) and (k)) Develop applications to minimize the requirement for synthetic chemical inputs in agricultural production processes (see programme area A);›

(c) ‹(Paras. 19 (b), (j)) Develop processes to reduce waste generation, to treat waste before disposal, and to make use of biodegradable materials;› 13/

(d) ‹(Para. 19 (a)) Develop processes to recover energy and provide renewable energy sources, animal feed and raw materials from recycling organic waste and biomass;›

(e) ‹(Para. 19 (i)) Develop processes to remove pollutants from the environment where conventional techniques are not available or are expensive, inefficient, or inadequate;›

(f) ‹(Para. 19 (1)) Develop processes to increase the availability of planting materials, particularly indigenous varieties, for use in afforestation and reforestation and to improve sustainable yields from forests;› 14/

(g) Develop applications to increase the availability of stress tolerant planting material for land rehabilitation and soil conservation; 15/

(h) ‹(Para. 19 (d)) Increase the use of integrated pest management based on the judicious use of bio-control agents;›

(i) ‹(Para. 19 (e)) Increase the appropriate use of bio-fertilizers within national fertilizer programmes;›

(j) Promote the use of relevant biotechnologies for the conservation, including sustainable use, of biological diversity; 16/

(k) Develop easily applicable technologies for the treatment of sewage and organic waste.

(b) Data and information

27. The following activity should be undertaken:

Take steps to increase access to existing information and to facilities based on global databases.

(c) International and regional cooperation and coordination

28. The following activities should be undertaken:

(a) ‹(Para. 19 (g)) Develop a framework of international agreements for training, research and development, particularly for developing countries, to support the activities outlined in this programme area;›

(b) Develop mechanisms for scaling up and marketing research findings and for adopting environmentally-sound biotechnologies with possibly limited commercial potential, especially in the short term, but of high environmental priority;

(c) ‹(Para. 19 (m)) Enhance biotechnological cooperation (other than direct transfer of technology) between participating countries for capacity-building.›

4. Means of implementation

(a) Financing and cost evaluation

29. The estimated average annual cost of this programme area could be upwards of US$ 1 billion, of which it is estimated that about US$ 10 million would come from international financing sources.

(b) Scientific and technological means

30. See paragraphs 26 (a)-28 above.

(c) Human resource development

31. The activities for this programme area will increase the demand for trained personnel. Support for existing training programmes needs to be increased (e.g., at the university and technical institute level). New and additional training programmes also need to be developed (e.g., technical and support personnel). There is also an urgent need to improve the level of understanding of biological principles and their policy implications by decision makers in Governments, and financial and other institutions.

(d) Capacity-building

32. Relevant institutions will need to have the responsibility and capacity (political, financial and manpower) to undertake the activities and to be dynamic in response to new biotechnological developments. Programme area E contains further details.

D. Enhancing safety and developing international mechanisms for cooperation

1. Basis for action

33. ‹(Para. 20) When adequate and transparent safety procedures are in place, the community at large will be in a much better position to accept the potential benefits of biotechnology. There is a need for internationally acceptable and agreed technical safety procedures, which should build upon procedures that are already developed at the national and international levels. Several fundamental principles underlie many of these safety procedures, as follows:

(a) Primary consideration of the organism, including genetically modified organisms;

(b) Application of the step-by-step procedure;

(c) Complementary consideration of risk assessment and risk management;

(d) Classification into contained use or release to the environment;

(e) A framework for safety in biotechnology.›

2. Objectives

34. ‹(Para. 21) The aim of this programme area is to enhance safety in biotechnology development and application through international cooperation, with particular reference to social, health and environmental considerations, including the widest possible public participation.›

3. Activities

(a) Management-related activities

35. ‹(Para. 22) The proposed activities for this programme area call for close international cooperation. They should build upon planned or existing activities to accelerate the environmentally sound application of biotechnology, especially in developing countries, with particular reference to the sections entitled "International cooperation on safety in biotechnology" and "Areas for further work" contained in document A/CONF.151/PC/67, as follows:›

(a) ‹(Para. 22 (a)) Make the existing safety procedures widely available by collecting the existing material and adapting it to the specific needs of different countries and regions;›

(b) ‹(Para. 22 (b)) Further develop the existing safety procedures to promote scientific development and categorization in the areas of risk assessment and risk management (information requirements, databases, procedures for assessing risks, establishment of safety conditions, monitoring and inspections);›

(c) ‹(Para. 22 (c)) Harmonize the safety procedures into a framework of internationally agreed technical guidelines on safety in biotechnology as a basis for further development;›

(d) Undertake training programmes at national and regional levels on the application of the proposed technical guidelines;

(e) ‹(Para. 22 (c)) Consider the possibility of developing an international code of conduct, taking account of decision 1/17 of the Preparatory Committee at its first session.›

(b) Data and information

36. See paragraphs 35 and 37.

(c) International and regional cooperation and coordination

37. See paragraph 35. Further activities should include the following:

(a) Organize one or more regional meetings between countries to identify further practical steps to facilitate international cooperation in bio-safety; 17/

(b) ‹(Para. 22 (d)) Establish an international network incorporating national, regional and global contact points;›

(c) ‹(Para. 22 (e)) Provide direct assistance upon request through the international network, using information networks, databases and information procedures.›

4. Means of implementation

(a) Financing and cost evaluation

38. The estimated average annual cost of this programme area for the period 1993-2000 could be about US$ 2 million, all of which would come from international sources.

(b) Scientific and technological means

39. See paragraph 35.

(c) Human resource development

40. See paragraph 35.

Capacity-building

41. ‹(Para. 22 (f)) Adequate international technical and financial assistance should be provided and technical cooperation to developing countries should be facilitated in order to build up technical, managerial, planning and administrative capacities at the national level to support the activities in this programme area.› See also programme area E.

E. Establishing enabling mechanisms for the environmentally sound application of biotechnology

1. Basis for action

42. ‹(Para. 23) The accelerated development and application of biotechnologies, particularly in developing countries, will require a major effort to build up institutional capacities at the national and regional levels. In developing countries, "enabling" factors such as training capacity, know-how, R&D facilities and funds, industrial building capacity, capital (including venture capital) and expertise in such areas as marketing research, technology assessment, socio-economic assessment and safety assessment are frequently inadequate. Efforts will therefore need to be made to build up capacities in these and other areas and to match such efforts with appropriate levels of financial support. There is therefore a need to strengthen the endogenous capacities of developing countries by means of new international initiatives to speed up the development and application of both new and conventional biotechnologies to serve the needs of sustainable development at local, national and regional levels. 18/

43. Some activities at the national, regional and global levels already address the issues outlined in programme areas A, B and C. Several others are related to programme area D, particularly with respect to the international harmonization of safety guidelines in biotechnology, and to providing advice to individual countries on the development of national guidelines and systems for their implementation. These activities are generally uncoordinated, however, involving many different organizations, priorities, constituencies, timescales, funding sources and resource constraints. There is a need for a much more cohesive and coordinated approach to harness available resources in the most effective manner.›

2. Objectives

44. The objectives are:

(a) ‹(Para. 24) To accelerate the environmentally sound and safe development and application of biotechnologies, particularly in developing countries, by:

(i) Adding value to existing efforts at national, regional and global levels;

(ii) Mobilizing additional financial resources and instituting innovative financing mechanisms as necessary for selected priorities to suit the specific needs of different regions or socio-economic conditions;

(iii) Providing the necessary political support for biotechnology at the national and international levels;

(iv) Raising public awareness as to the beneficial aspects of biotechnology, to contribute to environmental conservation and sustainable development;

(v) Promoting basic research, as well as product development;

(vi) Helping to create a favourable climate for investments, industrial capacity building and distribution/marketing;

(vii) Helping to provide conditions for trained scientists in developing countries to remain voluntarily in their countries, and to ensure that investments lead to socio-economic progress;

(b) To identify ways and means of enhancing current efforts, building wherever possible on existing enabling mechanisms, to determine the precise nature of the needs for additional initiatives, particularly in respect of developing countries, and develop appropriate response strategies, including proposals for any new international mechanisms, by [1994].›

3. Activities

(a) Management-related activities

45. The following activities should be undertaken:

(a) ‹(Para. 25 (c)) Develop policies and mobilize additional resources to facilitate greater access to the new biotechnologies, particularly by and among developing countries;› 19/

(b) ‹(Para. 25 (h)) Implement programmes to create greater awareness of the potential benefits of the environmentally sound application of biotechnology among the public and key decision makers;›

(c) ‹(Consolidation of paras. 25 (a) and (b)) Undertake an urgent review of existing enabling mechanisms, policies, programmes and activities at national, regional and global levels to identify strengths, weaknesses and gaps, and to assess the priority needs of developing countries;› 20/

(d) ‹(Consolidation of paras. 25 (d) and (g)) In the light of paragraph 45 (e) below, undertake an urgent follow-up review to identify ways and means of strengthening endogenous capacities within and among developing countries for the environmentally sound application of biotechnology, including the consideration of possible new international mechanisms;› 21/

(e) Define and implement policies to overcome constraints identified in the areas of food, feed and renewable raw materials, human health and environmental protection and build upon existing strengths; 21/

(f) Develop strategic plans for overcoming targeted constraints by means of appropriate research, product development and marketing;

(g) Establish additional quality assurance standards for biotechnology applications and products where necessary.

(b) Data and information

46. The following activities should be undertaken:

Facilitate access to existing information dissemination systems, especially by and from developing countries, and improve such access where appropriate.

(c) International and regional cooperation and coordination

47. The following activities should be undertaken:

Develop appropriate new initiatives, especially at the international level, including the consideration of possible cooperative commercial ventures among developing countries to strengthen endogenous capacities and engage in biotechnology research, development and application. 21/

4. Means of implementation

(a) Financing and cost evaluation

48. The estimated average annual cost of this programme area for the period 1993-2000 could be about US$ 5 million, all of which would come from international financing sources. This does not include the costs of any innovative mechanisms arising from the implementation of this programme area. 22/

(b) Scientific and technological means

49. Workshops, symposia, seminars and other exchanges among the scientific community at regional and global levels, on specific priority themes, will need to be organized, making full use of the existing scientific and technological manpower in each country for bringing about such exchanges.

(c) Human resource development

50. Personnel development needs will need to be identified and additional training programmes developed at the national, regional, and global levels, and especially in developing countries. These should be supported by increased training at all levels - graduate, postgraduate, post-doctoral, as well as technicians and support staff, with particular reference to the generation of trained manpower in consultant services, design, engineering and marketing research. Training programmes for lecturers to train scientists and technologists in advanced research institutions in different countries throughout the world will also need to be developed, and systems instituted for giving appropriate rewards, incentives and recognition to scientists and technologists (see para. 49 above). Conditions of service will also need to be improved at the national level in developing countries to encourage and nurture trained manpower with a view to retaining it locally.

(d) Capacity-building

51. ‹(Para. 25 (h), subparas. (i) and (v)) Biotechnology research and development is undertaken both in highly sophisticated conditions and at the practical level in many countries. Efforts will be needed to ensure that the necessary infrastructure facilities for research, extension and technology activities are available on a decentralized basis. Global and regional collaboration for basic and advanced research and development will also need to be further enhanced and every effort made to ensure that existing national and regional facilities are fully utilized. Such institutions already exist in some countries and it should be possible to make use of them for training purposes and joint research projects. Strengthening of universities, technical schools and local research institutions for the development of biotechnologies and extension services for its application will need to be developed, especially in developing countries.› 23/

Notes

1/ Biotechnology comprises a continuum of technologies, ranging from long-established and widely used technologies, which are based on the commercial use of microbes and other living organisms, to more strategic research on genetic engineering of plants and animals. Biotechnology includes any technique that uses living organisms, or substances from those organisms, to make or modify a product, to improve plants or animals, or to develop micro-organisms for specific uses. This applies to both traditional and modern biotechnology. Traditional biotechnology covers well-established

Notes (continued)

technologies used in commercially useful operations, such as the technologies long used in brewing, biological control of pests, conventional animal vaccine production, among many others. Modern biotechnology, on the other hand, encompasses the use of more recently available technologies, particularly those based on the use of recombinant DNA technology, monoclonal antibodies, and new cell and tissue techniques.

2/ ‹(Para. 6) The programme areas in this document focus on five principal objectives:

(a) Increase the productivity of agro-forestry systems for the production of food, feed and renewable raw materials, through the use of modern and traditional technologies;

(b) Contribute to major improvements in human health on a global scale;

(c) Contribute to preserving the environment and reducing environmental degradation by the judicious application of biotechnology and facilitate the increased provision of safe, clean and reliable water supplies;

(d) Assist in the implementation of effective procedures for the continued safe use of biotechnology;

(e) Stimulate the greater use of biotechnology in developing countries.›

3/ See section I, chapter 4 of Agenda 21 (Demographic dynamics and sustainability).

4/ Early applications of new biotechnologies in the agriculture sector may include:

(a) Crop production

(i) New diagnostics for the detection of pests and diseases;

(ii) Improved methods of cell and tissue culture to permit the more rapid propagation of plant and tree species;

(iii) New crop varieties with improved tolerance to pests and diseases and/or higher yields;

(iv) New biological control agents to reduce pesticide use;

(v) Genetic mapping as an aid to plant breeding programmes.

When new diagnostics and propagation methods are combined, they can permit the rapid propagation of pest and disease-free planting material, opening up the possibility of significant increases in yields, especially for

Notes (continued)

crops propagated from clones such as potatoes and sugar cane. More rapid propagation systems are especially useful for recalcitrant and/or slow-growing tree species (e.g., eucalyptus), which do not easily propagate through seed.

The major route for the application of new biotechnologies in crop agriculture is likely to be through the development of new crop varieties with improved yields, resistance to pests and diseases and/or tolerance to environmental stresses such as drought or salinity. The development of new plant varieties with such desirable characteristics will require the integration of the new techniques of modern biotechnology into conventional plant breeding programmes.

New genetic mapping techniques are becoming increasingly important to plant breeding programmes for the selection of lines with particular characteristics (e.g., tolerance to drought or to particular pests). Transgenic crops that confer resistance to certain pests and pathogens are now being field tested in many industrial and some developing countries. For example, it is expected that insect-resistant cotton plants will be available in 1993; this proprietary transgenic cotton germ plasm could also be shared with developing countries, which grow most of the world's cotton production. Similarly, food crops such as potatoes and tomatoes expressing non-conventional virus resistance due to viral coat protein genes are being field tested in several countries. Such strains could be commercially available within the next few years.

These developments in cotton and vegetables, which consume 30 per cent of the insecticides applied annually, offer all countries an opportunity to take advantage of new biotechnology products in the near- to mid-term. Utilization of transgenic pest-resistant plants should allow productivity to be increased on a more sustainable basis by the use of alternatives to chemical insecticides, with greater emphasis on the use of integrated pest management systems, primarily based on the use of biological control techniques and host plant resistance, rather than on the use of chemical pesticides. The long-term potential environmental aim for cotton and vegetable technologies is to substitute up to 20 per cent of the current US$ 6 billion per year used on chemical insecticides. Bacillus virus is already being used to control soybean insect pests on more than 1 million hectares of land in developing countries. Increasing efficiencies of nitrogen fixation in leguminous crops and improving nitrate uptake capacity also offer near- to mid-term opportunities for developing alternatives to chemical nitrogen fertilizers; biological nitrogen fixation in non-leguminous crops is a longer term prospect.

In the animal feed area, the development of high lysine corn has demonstrated the type of gains in nutritional value which can be obtained by the judicious use of technology. Recently, varieties of lipoxygenase-free soybean have been developed, whose flavour makes them better suited for human consumption.

Notes (continued)

(b) Livestock production

(i) Embryo technology, especially for cattle;

(ii) New vaccines against infectious diseases;

(iii) Improved disease diagnostics;

(iv) Genetic mapping for livestock-breeding programmes.

(c) Agriculture

(i) Rapid methods for disease monitoring by improved diagnostics;

(ii) Improved methods for feed formulation and storage.

(d) Microbial biological processing

The use of new bio-processing techniques based on microbial fermentation is likely to lead to the production of new value-added products (e.g., higher nutrition foods and new antibiotics).

5/ Advanced aquaculture techniques will allow more productive cultivation and harvesting from the aquatic environment. Such techniques include genetic manipulation of the aquatic species to disease resistance, temperature tolerance, salinity tolerance, among other stresses, but also for improved nutritive value of the species. However, the creation of new races of aquatic species might impact adversely on the delicate relationships among other species and may lead to severe environmental problems. The issue is comparable to importing an exotic species into a new environment, where, finding no natural enemies (disease or predators), it flourishes and multiplies exponentially. In terrestrial systems this has been evidenced in numerous cases, with the exotic species out-competing endemic species to the point of elimination, or, in some cases, extinction.

6/ The priority is to accelerate product development from the R&D phase to large-scale production and adoption.

7/ Including chapters on agriculture, health and hazardous wastes.

Both the amount and the proportion of the global investments currently made by developing countries in biotechnology research and development need to be increased substantially during the period 1993-2000 and beyond to enable them to take advantage of the growing opportunities that biotechnology has to offer for accelerated development.

8/ The vaccines should preferably be stable at higher temperatures and be deliverable orally.

Notes (continued)

9/ Possible examples include insulin, growth hormone, immuno-modulators and other therapeutic agents.

10/ Possible examples include identification of receptor-drug/receptor-pathogen interactions through computer simulation and modelling.

11/ Possible examples include site-specific delivery and oral formulations.

12/ Possible examples include biocatalysed processes to replace energy-intensive synthetic chemical processes.

13/ Possible examples include enhanced biological sewage treatment.

14/ Possible examples include rapid multiplication of planting material.

15/ Possible examples include variety development, selection techniques and rapid multiplication of planting material.

16/ Applications can include propagation techniques for in situ conservation and tissue culture, hybridization techniques, cryopreservation and embryo transfer for ex situ conservation.

17/ Such meetings could be held with expert support from organizations such as the United Nations Environment Programme (UNEP), the World Health Organization (WHO), the United Nations Industrial Development Organization (UNIDO), the General Agreement on Tariffs and Trade (GATT) and the Organisation for Economic Cooperation and Development (OECD) to identify practical steps to facilitate the development of procedures at the national level to capitalize on work already undertaken on harmonization on technical matters, to determine the kind of administrative machinery required to implement such technical arrangements and to contribute to minimizing the differences in requirements in countries to promote the best possible climate for international trade and safe development of biotechnology.

18/ Some of the technologically more advanced developing countries have already initiated programmes and activities for the development of biotechnology. Some have even introduced tissue culture and RDNA-based products into their national markets and have identified a 10-25 year biotechnology programme perspective. Major investments in modern biotechnology are being made at the national level in several Asian and Latin American countries. More modest investments are also being made in African countries, with an increasing interest in how modern biotechnology could help improve food security and sustainable development in Africa. However, a large number of countries have neither the capacity nor the resources necessary to do this. Even in those developing countries which have made significant progress in biotechnology, the underlying skill and financial base and the capacity to formulate and implement programmes are frequently extremely weak.

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The gap between technological and financial needs and what is available at the national level appears to be widening. As a result, most developing countries are unlikely to be in a position to acquire, absorb and afford technologies and products as they become available from developed countries.

Among international development organizations, several have been supporting substantial programmes over the past decade, covering some of the activities outlined in programme areas A, B, C and D. Existing programmes include those supported by:

(a) United Nations organizations (e.g., the United Nations Development Programme (UNDP), the Food and Agriculture Organization of the United Nations (FAO), the United Nations Educational, Scientific and Cultural Organization (UNESCO) and UNIDO);

(b) Multilateral development banks (e.g., World Bank, African Development Bank, Inter-American Development Bank);

(c) Multilateral agencies (e.g., European Community);

(d) Bilateral development agencies;

(e) Regional organizations (e.g., Association of South-East Asian Nations (ASEAN), Inter-American Institute of Agricultural Sciences (IICA));

(f) Private foundations (e.g., Rockefeller Foundation);

(g) Consultative Group on International Agricultural Research (CGIAR) and its International Agricultural Research Centres (IARCs).

Other possible models of international collaboration include the Special Programme of Research, Development and Research Training in Human Reproduction (HRP), sponsored by UNDP, the United Nations Population Fund (UNFPA), WHO and the World Bank. The Special Programme mobilizes a global partnership between scientists, scientific institutions and decision-making groups in more than 80 countries. International assistance should also provide quality assurance programmes and undertake feasibility studies to serve as catalysts for both private and government investments. The Special Programme is funded by voluntary contributions, currently amounting to about US$ 23 million per year.

19/ This could include the provision of information and advice to Governments on the role, costs and benefits of intellectual property management, taking account of the concept of "farmers' rights" as a means of compensating local communities for their custodianship of biological resources; and the fostering of greater private-sector involvement in biotechnology in developing countries, both by local firms and by transnational companies.

Notes (continued)

20/ Any additional initiatives to mobilize further support for, add value to and promote the environmentally sound application of biotechnology should build upon and enhance relevant existing activities. The experience of existing agencies currently involved in this field should be sought in any review. Several agencies have previously examined these issues and a number of initiatives are in place or are being developed at different levels and scales in various countries.

Current activities range from basic research to product development and application. They include the activities of international laboratories (e.g., the International Centre for Genetic Engineering and Biotechnology (ICGEB)), several United Nations regional organizations, many Governments, non-governmental organizations, private companies, universities and other academic research institutions. Many different types of collaboration, involving various combinations of institutions currently take place, including bilateral and multilateral cooperation, as well as various combinations of public and private funding.

Possible terms of reference for the first stage of a two-part review might include the following:

(a) Assessment of the strengths and weaknesses of existing mechanisms at national, regional and global levels and identification of gaps;

(b) Assessment of national and regional needs and priorities. Most developing countries need expert advice and assistance for determining priorities and for strategic planning in the use of various biotechnology developments for the production and use of new products and technologies. Many needs and problems are local (regional within individual countries and between countries from the same region). Priorities and needs vary from one region to another and would depend on the status of technology and products and the needs of a region. The implementation capability in the region in terms of skilled manpower, infrastructure and affordability, and perceived national priorities would also need to be carefully considered;

(c) Identification of existing or previous biotechnology-related development activities and assessment of their impact, noting successes and failures;

(d) Assessment of other constraints to the development of biotechnology, especially in developing countries;

(e) Recommendations as to the types of measures required to address the gaps, priorities and assistance needs (e.g., human resources, mechanisms and financing) to accelerate the development of the environmentally sound application of biotechnology, especially in developing countries.

Notes (continued)

21/ The purpose of the second stage of a review would be to consider the need for and the possible nature of improved or new mechanisms to enable developing countries in particular to accelerate the development, acquisition and adaptation of non-proprietary biotechnologies, taking account of the recommendations emerging from the first stage. This could include consideration of possible cooperative commercial ventures between developing countries.

Any possible initiative for improved or new enabling mechanisms would need to build upon and enhance the strengths and capacities of existing institutional mechanisms, such as the GCIAR/IARC network, ICGEB, Latin American Cooperation in Biotechnology, relevant United Nations organizations, the World Bank and other development banks, bilateral programmes and international aid programmes, as well as the activities of transnational corporations. Ideally, any such mechanism would:

(a) Address itself specifically to regional or national problems;

(b) Possess the necessary scientific and technological capability, including research and development capacities, for addressing those problems;

(c) Possess the appropriate financial and managerial strengths to underwrite and implement programmes on a sound commercial basis;

(d) Enable participating countries to share the benefits (including possible profits) of its activities;

(e) Take account of the special need for effective cooperation between genetically rich developing countries and those developed countries with relevant biotechnology capabilities, with particular reference to the special role of local and indigenous communities;

(f) Examine any need for possible mechanisms on the liability and compensation aspects of the unanticipated impacts of biotechnology applications.

The functions of any such mechanism might include:

a/ Programme planning: Building upon the priority assessment procedures arising from the review referred to in paragraph 45 (c) above, national/regional strategic planning of various resources (including research and development options and costs), assessment of supporting needs and institutional networking might be undertaken as part of a comprehensive programme planning exercise. This ought to enable assessments to be made of the techno-economic feasibility and socio-economic relevance of potential products and applications as the basis for sound commercial decision-making. The need for and marketability of individual products and applications would also need to be clearly established prior to incorporation into national programmes as appropriate.

Notes (continued)

b/ Programme implementation: Detailed project reports on the techno-economic feasibility of large-scale production and marketing of products and applications and the potential socio-economic benefits. A possible capability for assessing, monitoring, providing, mobilizing and counselling might also be considered backed by an "honest broker" approach to ensure a reasonable return on investments.

The nature and structure of any such mechanism would clearly depend upon the outcome of any review.

22/ On a global basis, there are limitations on the availability of venture and investment capital and public sector research and development funds. Given that biotechnology projects are regarded as high risk ventures, innovative funding mechanisms will be necessary to overcome these constraints. The possibilities which offer potential for maximizing the effect of both private and public sector spending in initiating and applying biotechnology developments include:

(a) Stimulation of cooperation between companies and public research organizations by establishing joint ventures;

(b) Tax concessions on R&D expenditure;

(c) Patent extensions or increases in fixed sale price on existing products in exchange for R&D expenditure on projects unlikely to provide returns on investment (e.g., vaccines for diseases in developing countries);

(d) Equity or royalty considerations to host countries on the sale of products derived from trials and demonstrations;

(e) Introduction of offsets obligation on major contracts and equipment supply to be discharged by expenditure on contract R&D, technology transfer etc.

The amount of existing financial investments in modern biotechnology by public and private sector agencies, at the national, regional and global levels (including investments by bilateral and multilateral development organizations) will need to be identified. It will also be necessary to review existing financial mechanisms, identify any constraints to their efficient operation, suggest ways to alleviate those constraints and consider how such mechanisms might be strengthened or supplemented. This might include the development of innovative mechanisms for compensating opportunity costs forgone in the light of any restrictions on the exploitation of biological resources to protect the environment.

23/ Steps to be taken should include ‹(para. 25 (h)) mobilizing appropriate levels of scientific and technical assistance to, and cooperation with, developing countries, especially with a view to:›

Notes (continued)

(a) ‹(Para. 25 (h), subpara. (i)) promoting the development of endogenous research within the public and private sectors;›

(b) ‹(Para. 25 (h), subparas. (ii) and (v)) promoting the conservation of biological and genetic resources in developing countries, with particular recognition of the skills and knowledge of indigenous communities in the fields of traditional medicine and phytotherapy and the linkages of biotechnology with the relevant aspects of biodiversity;›

(c) ‹(Para. 25 (h), subpara. (iii)) Creating awareness at all levels, including policy making, administration, politicians, the general public, through mass media, publications, workshops and interactive mechanisms.›